K111949
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510(k) Summary

JUN 29 2012

Date Prepared	June 25, 2012	
Sponsor Information	NanoVibronix, Inc. 105 Maxess Road, Suite S124 Melville, NY 11747	807.92(a)(1)
Sponsor Contact	Harold Jacob	
Title	CEO	
Phone	1-516-668-3185	
Device Name/Trade Name	AC Wound Management System	807.92(a)(2)
Common/Usual Name	Negative Pressure Wound Therapy Pump	
Classification Name	Powered Suction Pump	
Regulation Number	21 CFR 878.4780	
Product Code	OMP	
Review Panel	Surgical, Orthopedic, and Restorative Devices	
Device Classification	Class II	

Predicate Device

807.92(a)(3)

Company Name	Brand Name	510K Number
Smith & Nephew, Inc.	Renasys™ GO Negative Pressure Wound Therapy	K083375

Device Description

807.92(1)(4)

The AC Wound Management System is a powered suction pump that utilizes a pump drive to generate light negative pressure. The pump drive is powered by a rechargeable battery. Optionally the unit can be connected to mains power using an included power converter.

AC Wound Management System has a negative pressure setting range of -50 mmHg to -175 mmHg which is electronically monitored and controlled. The system includes a keyboard for user interface as well as audible and visual alarm indicators. The system includes a 300cc canister. The system can be set on a countertop, carried using a shoulder bag or mounted to an IV pole or bedside rail using the AC Wound Management System's mount.

The AC Wound Management System includes the following three components:

- The pump drive.
- The waste canister, with its suction tube (the two are connected permanently).
- FDA cleared generic NPWT dressing, which will be distributed by NanoVibronix.

The pump drive is a non-disposable unit which contains a motor, a battery and a user interface. The drive has a piston which protrudes the drive and reciprocates to activate the suction pump, which is integral to the canister. In the drive there is also a vacuum level monitor which monitors the vacuum at all times and maintains the required set therapy.

The waste canister attaches to the drive. The pump creates vacuum within the waste canister for the purpose of suctioning exudates from the wound and collecting them in the canister. The canister has a hydrophobic filter.

The suction tube connects the waste canister to the wound dressing applying the vacuum generated within the waste canister to the wound site. The tube also transfers the exudates from the wound to the waste canister by maintaining flow from the wound site towards the waste canister at all times.

Indications for Use

807.92(a)(5)

AC Wound Management System is indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by removing fluids, including irrigation and body fluids, wound exudates, and infectious materials. Examples of appropriate wound types include: Diabetic/Neuropathic ulcers, Pressure ulcers, Chronic wounds, Acute wounds, Dehisced wound, Partial-thickness burns, and Flaps and Grafts.

Predicate Product Comparison Table

807.92(1)(6)

Parameters	NanoVibronix, Inc. AC Wound Management System	Smith & Nephew, Inc. Renasys Go
510(k) Number		K083375
Indications for Use	AC Wound Management System is indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by	Renasys Go is indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by removing fluids including

	removing fluids, including irrigation and body fluids, wound exudates, and infectious materials. Examples of appropriate wound types include: Diabetic/Neuropathic ulcers, Pressure ulcers, Chronic wounds, Acute wounds, Dehisced wound, Partial-thickness burns, and Flaps and Grafts.	irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.
Mode of Operation	Continuous or Intermittent	Continuous or Intermittent
Maximum negative pressure	-175mmHg	-200 mmHg
Negative Pressure Therapy Settings	-50mmHg, -75mmHg, -100mmHg,-125mmHg, -150mmHg, -175mmHg	From -40 mmHg to -200mmHg
Power Requirements	Input: 100-240V AC 50/60Hz 0.6A Output: 12V DC, 2.08A, 5W	Input: 100-240V AC 50/60Hz 0.9A Output: 21V DC, 1.71A, 36W
Battery Type	Lithium ion rechargeable	Lithium ion rechargeable
Battery Operating Time	~20 hours (therapy)	~ 20 hours (therapy)
Dimensions	190x140x70mm (7.4 x 5.5 x 2.7 inches)	175x210x85mm (7 x 8.3 x 3.5 inches)
Weight	0.82kg (1.8 lbs)	1.1kg (2.4lbs)
Operating Environment	5-35°C (41-95°F) 30 to 70% RH 700 to 1060 mbar atmospheric pressure	5-35°C (41-95°F) 30 to 70% RH 700 to 1060 mbar atmospheric pressure
Canister Capacity	300 ml	300 ml

Comparative Bench Testing

807.92(b)(1)

A comparative bench test was performed to determine the substantial equivalence of the AC Wound Management System to the Renasys™ Negative Pressure Wound Therapy System.

1. The results of the tests show that both - AC NPWT system and predicated device Renasys NPWT system - provide stable operation.

2. The results were obtained for three negative pressure levels: -50mmHg, -100mmHg and -175mmHg. Test duration was 72 hours for each level.
3. For both systems the deviation between determined negative pressure level and measured average negative pressure level was no more then 1% (in four measurement points).
4. We conclude that AC NPWT system overcomes the acceptance criteria

Electrical and Bench Tests

AC Wound Management System complies with IEC 60601-1 and IEC 60601-1-2 Standards.

Bench test	Results
Electrical Safety	Test results demonstrated compliance with the standard.
EMC Compatibility	Test results demonstrated compliance with the standard.
Firmware verification	Test results demonstrated compliance with labeling and the standard.
Functionality test	Test results demonstrated compliance with labeling and the standard.
Pressure stability test for pump	Test results positive
Battery test	Test results demonstrated 20 hours work therapy (max pressure, continuous mode)
Labeling	Device comply with standards

Packaging	Device comply with requirements

Clinical Tests

807.92(b)(2)

No clinical studies were conducted.

Conclusion

807.92(b)(3)

The AC Wound Management System and the Renasys™ Negative Pressure Wound Therapy System have the same indications for use and modes of operation. Both products use rechargeable battery, have same canister capacity, use similar pressure settings and have similar dimensions & weight. Therefore, the AC Wound Management System does not raise any new issues of safety and effectiveness. The AC Wound Management System is substantially equivalent to the Renasys™ marketed device and is safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AC Wound Treatment System
% Smith Associates
Mr. EJ Smith
1468 Harwell Avenue
Crofton, Maryland 21114

JUN 29 2012

Re: K111949
Trade/Device Name: AC Wound Management System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered sunction pump
Regulatory Class: Class II
Product Code: OMP
Dated: June 15, 2012
Received: June 15, 2012

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111949

Indications for Use

510(k) Number (if known): _____

Device Name: AC Wound Management System

Indications for Use:

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Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111949